K042164

JUN 9 - 2005

510(k) Summary

Sponsor:	Medline Industries One Medline Place Mundelein, Il 60060
Contact Person:	Dr. Bruce L. Gibbins; (503)-624-9830
Device Name	Silver Antimicrobial Wound Gauze for external use
Common Name:	Gauze Sponge/Bandage
Classification and Panel:	Unclassified; General and Plastic Surgery

Legally marketed device(s) for substantial equivalence comparison:

SilvaSorb Silver Antimicrobial Wound Dressing (AcryMed, Inc., OR)
Kerlix AMD (Kendall, MD)
Bulkee Gauze/Avant Gauze Sponge (Medline, IL)
Aquacel Ag (Convatec, NJ)

Description of Device: The new product is a non-X-ray detectable, non-absorbable gauze sponge/bandage consisting of cotton, rayon/polyester formed material that has been treated with proprietary silver saccharinate which can give rise to ionic silver when put into contact with aqueous moisture such as that in wound fluid. Sterile gauze sponges and bandages of various sizes and formats in individual single use packaging are for use as primary or secondary wound dressings. Sterility assurance will conform to AAMI/ANSI/ISO 11137-1994.

Intended Use of the Device: Silver Antimicrobial Gauze Sponge/Bandage devices are indicated for external use only. These devices are intended for use in the management of Pressure ulcers, Stasis ulcers, Diabetic foot ulcers, First and second degree burns, Lacerations, Abrasions, Skin tears, Surgical incision sites, Graft sites, and Donor sites.

Technological Characteristics: The Silver Antimicrobial Wound Gauze is an antimicrobial barrier wound covering that gives rise to ionic silver when in contact with aqueous moisture. Ionic silver possesses antimicrobial activity when in a moist environment such as when contaminated by bodily fluids including wound exudate.

Pre-Clinical Testing: The new product has been shown to possess antimicrobial activity against 29 strains of bacteria, fungi and yeasts in vitro including *E. coli* (2 strains), *Klebsiella pneumoniae* (3 strains), *Candida albicans* (3 strains), *Candida parapsilosis, Staphylococcus aureus,* Methiacillin Resistant *Staphylococcus aureus* (2 strains), coagulate negative *Staphylococcus aureus, Pseudomonas aeruginosa* (3 strains), *Bacillus subtilis, Enterobacter cloacae* (2 strains), *Enterococcus faecalis* (2 strains), Vancomycin Resistant *Enterobacter faecium* (2 strains), *Aspergillus niger, Serratia marcescens, Candida galbrata, Citrobacter diversus, Citrobacter kasseri, and Staphylococcus saprophyticus.* Silver antimicrobial wound gauze has been shown by in vitro serial transfer testing to be active for up to 5 days. Safety and biocompatibility assurance has been established in accordance with Part-1 of the ISO standard (*Biological Evaluation of Medical Devices*).

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Manufacturing: Silver Antimicrobial Wound Gauze will be manufactured according to the product specifications and under good manufacturing practices that ensure the device is safe and effective for its intended use.

Performance Standards: No performance standards are prescribed for the new product.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

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Medline Industries Incorporated
C/o Bruce Gibbins, Ph.D.
Chief Technical Officer
AcryMed Incorporated
12232 SW Garden Place
Portland, Oregon 97223

Re: K042164
Trade/Device Name: Silver Antimicrobial Gauze
Regulatory Class: Unclassified
Product Code: FRO
Dated: May 23, 2005
Received: May 24, 2005

Dear Dr. Gibbins:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

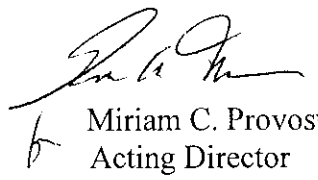
If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

This letter will allow you to begin marketing your device as described in your Section 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Office of Compliance at (240) 276-0115 . Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 443-6597 or at its Internet address http://www.fda.gov/cdrh/industry/support/index.html.

Sincerely yours,



Miriam C. Provost, Ph.D.
Acting Director
Division of General, Restorative
and Neurological Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

Indications for Use

510(k) Number (if known): K042164

Device Name: Silver Antimicrobial Gauze

Indications For Use:

Pressure ulcers
Stasis ulcers
Diabetic foot ulcers
First and second degree burns
Lacerations
Abrasions
Skin tears
Surgical incision sites
Graft site
Donor sites

Prescription Use ___X____ AND/OR Over-The-Counter Use _____
(Part 21 CFR 801 Subpart D) (21 CFR 807 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

(Division Sign-Off)
Division of General, Restorative and Neurological Devices

510(k) Number K042164